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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 4 : A61M 5/14, F04B 13/00, 43/00 F15B 1/04 | A1

(11) International Publication Number: WO 88/ 00841

(43) International Publication Date: 11 February 1988 (11.02.88)

(21) International Application Number: PCT/AU87/00255

(22) International Filing Date: 10 August 1987 (10.08.87)

(31) Priority Application Number: PH 7349

(32) Priority Date: 8 August 1986 (08.08.86)

(33) Priority Country: AU

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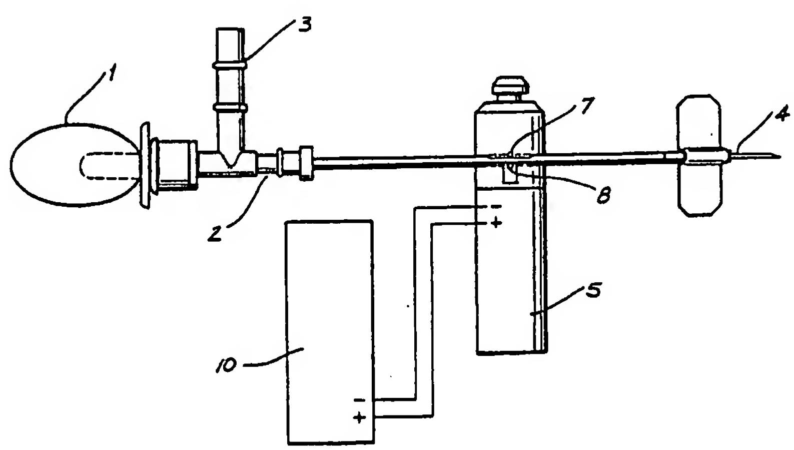
(81) Designated States: AT (European patent), AU, BB, BE (European patent), BG, BJ (OAPI patent), BR, CF (OAPI patent), CG (OAPI patent), CH (European patent), CM (OAPI patent), DE (European patent), DK, FI, FR (European patent), GA (OAPI patent), GB (European patent), HU, IT (European patent), JP, KR, LK, LU (European patent), MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL (European patent), NO, RO, SD, SE (European patent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent), US.

Published
With international search report.

(54) Title: EXPANSIBLE CHAMBER DRUG INFUSER SYSTEM



(57) Abstract

A pump suitable for the infusion of medicines comprises a elastic reservoir (1) adapted to contain medicines with an outlet controlled by a valve (7, 8). The pump utilizes the energy stored in the walls of the inflated reservoir to discharge the medicine from the reservoir. Preferably the valve is controlled by a programmable electronic timer (10) to regulate the flow of the medicine.

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EXPANSIBLE CHAMBER DRUG INFUSER SYSTEM

The present invention relates to an improved pump and, in particular, to a pulsatile pump or a continuous pump of small size.

Continuous and pulsatile pumps that accurately deliver specific volumes of fluids or drugs are applicable to large areas of medicine, industry and science.

In the field of medicine, fluids may be delivered intra-arterially, intravenously, subcutaneously into the lumen of the gastrointestinal tract, epidurally into the cerebrospinal fluid space or into a reservoir for delivery to a specific site. These pumps are usually of small sizes and are primarily mechanically driven syringes. These apparatus suffer from the disadvantages due to variation in resistance as the plunger is moved along the syringe and inertia in starting the motor and the moving of the plunger. Further, these mechanically driven syringes require relatively large quantities of energy and are therefore usually bulky due to the size of the motor and respective battery power source, and thus further require frequent battery changes.

The present invention seeks to ameliorate these disadvantages by providing a pump comprising:

an elastic reservoir;
an outlet; and
a valve located between said reservoir and said outlet; wherein

the reservoir is adapted to be filled under pressure by the liquid to be dispensed to inflate the elastic reservoir thus utilising the energy stored in the material of the reservoir to discharge the liquid from the reservoir.

Whilst the invention has many uses in both medicine, science and industry, the invention will now be described with reference to one embodiment suitable for use in medical field in which:

figure 1 illustrates a rechargeable silicone drug

infuser system according to one embodiment of the present invention;

figure 2 illustrates a control valve suitable for use with the system illustrated in figure 1; and

figure 3 illustrates the assembled system.

As shown in figure 1, the infuser system comprises a drug reservoir 1 made of silicone rubber attached to a three-way "T" piece 2. The port 3 has a one-way valve, which permits refilling of the reservoir, with the port 11 connected to a paediatric scalp vein needle 4.

A suitable control valve is shown in figure 2. This valve mechanism consists of a Dalrin cylinder (5) which has a slot (6) at right angles to the longitudinal axis to accommodate the silicone tubing which connects the "T" piece to the hypodermic needle. Once the tubing is fitted in this slot it is quite secure and can be neatly occluded by the two metal pins. The top pin (7) is fixed while the bottom pin (8) is attached at right angles to a shaft which is the central, moving part of the solenoid. This shaft travels up and down in the centre of the delrin cylinder. The pin (8) slides up and down in a longitudinal slot (9) in the side of the cylinder. A coil spring maintains tension on the shaft forcing the mobile pin against the stationary one squashing the tubing as it passes between the two pins.

With the pump as assembled in figure 3 activation of the solenoid draws pin 8 away from pin 7 and permits flow from the reservoir under pressure of the energy stored in the stretched material of the reservoir 1.

The duration of flow is controlled by a programmable electronic circuit contained in an "electronic controller" (10). The device is powered by a nine volt battery, the current drawn during activation of the solenoid is 125 - 175mA, otherwise the current drawn is negligible. A pulsing LED is attached to the electronic controller. It glows red if the battery power is waning or there is an electronic fault.

Thus this embodiment of the present invention can be worn, by patients requiring periodic or continuous

infusing of drugs, in a shoulder holster, in a pocket or on an arm band due to the small size of the device.

An alternative control mechanism is a flow restriction valve. By using a fine bore tube of .0005 inches (0.1mm) (length 1cm) in the flow restriction valve the flow can be limited to 5 mls/hour without the use of any electro-mechanical parts (pressure head of 250mmHg). Similarly by decreasing the lumen of our flow reduction valve to 0.008mm and by decreasing the durometer of our silicone reservoir, flow rates can be reduced to 0.5ml per hour. We believe this to be the lowest flow, gravity independent, constant infusion pump with no electro-mechanical parts available.

Preferably the reservoir is in the form of a balloon. Balloons are most frequently produced by rubber dipping, but this was not found to be satisfactory for this purpose. A liquid injected moulded technique was used to produce a rigid collar of 1mm thick sixty duro silicone rubber. This was sufficiently rigid to be tight snap fit onto a polypropylene hub. The hub was designed so that the maximum diameter of the hub was introduced into the silicone collar first. The hub of a balloon suitable for the present invention was tapered (5°) so that when pushed one centimetre into the collar the smallest diameter was at the leading edge of the collar and the largest diameter one centimetre down the collar. This design products a situation where enormous longitudinal pressures are required to detach the hub from the collar.

Above the collar a thin wall section measuring 15 millimetres in length and 4 millimetres in diameter with a wall thickness of 0.3 millimetres. This produces a firm semi rigid container which one would not expect to form a balloon on first visual inspection.

Pressures of 200 millimetres of mercury are required before the thin wall section starts to balloon. Between volumes of 2 and 8 mls there is a gradual rise in pressure to approximately 260 millimetres of mercury.

In the embodiment described the pulsatile system

delivers its fluid by using minimal quantities of energy to move a pinch valve fitting away from the tubing which it is obstructing. The energy for the obstruction is supplied by a spring while the energy for pumping fluid to the tissues is stored in the silicone wall. The majority of the energy required is therefore stored in the silicone rubber and in the spring. Only small batteries are therefore required.

The Continuous Flow System mode or embodiment delivers fluid at a relatively constant rate providing the elastic limit of the balloon is not exceeded upon filling. The flow is controlled by a flow reduction valve which may be constructed with a narrow lumen or a porous material. It is thereforea system which is gravity independent, and provides a constant flow rate above arterial pressures without the use of electromechanical energy to discharge the system.

It should be obvious to people skilled in the art that variation and alterations can be made to the above without departing from the scope or the spirit of the present invention.

THE CLAIMS

1. A pump comprising:

an elastic reservoir;

an outlet; and

a valve located between said reservoir and said outlet; wherein the reservoir is adapted to be filled under pressure by the liquid to be dispensed, to inflate the elastic reservoir, thus utilising the energy stored in the material of the reservoir to dispense the liquid from the reservoir.

2. A pump according to claim 1 wherein said valve is a pinch valve.

3. A pump according to claim 2 wherein said valve is a restriction valve.

4. A pump according to any one of the preceding claims wherein said elastic reservoir is in the form of a balloon.

5. A pump according to claim 5 wherein said balloon is made from silicone rubber.

6. A pump according to claim 6 wherein said balloon is formed by a liquid injection moulding technique.

7. A pump according to any one of the preceeding claims wherein said valve is controlled by a programmable electronic timer.

8. A pump substantially as herein before described with reference to the accompanying drawings.

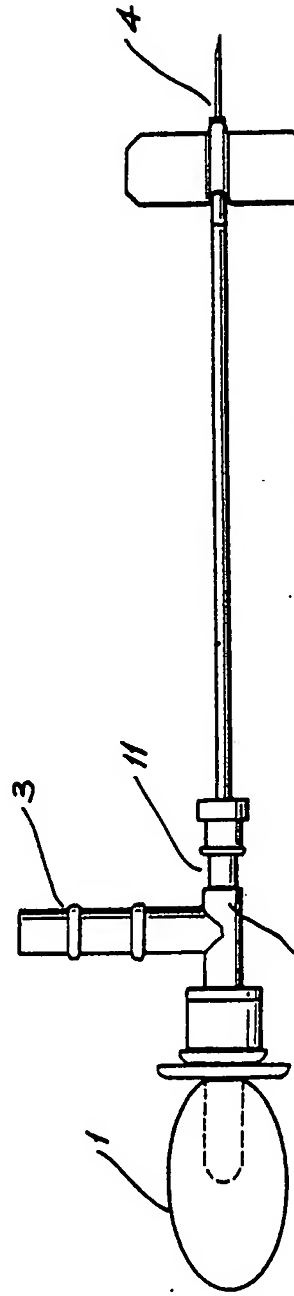

FIG. 1

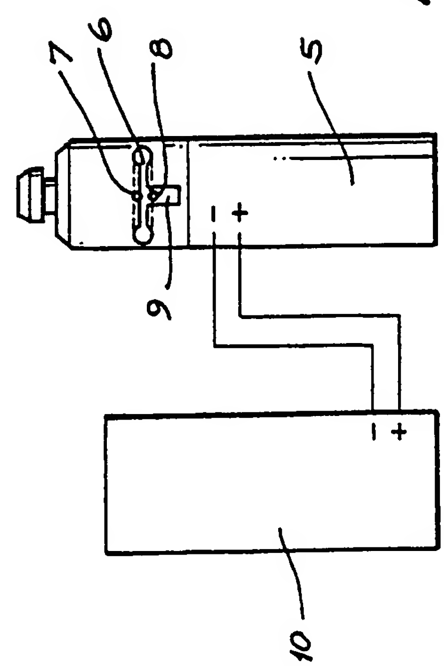

FIG. 2

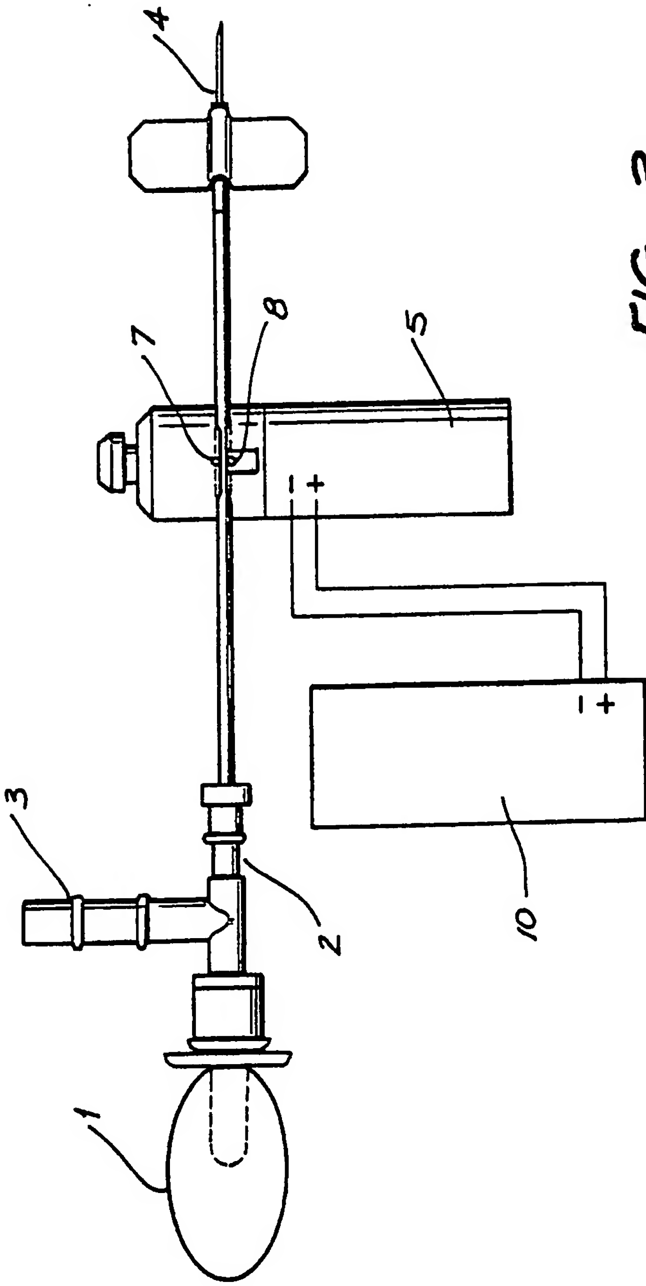

FIG. 3

INTERNATIONAL SEARCH REPORT

International Application No PCT/AU 87/00255

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl.[4] A61M 5/14, F04B 13/00, 43/00, F15B 1/04

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
IPC	A61M 5/14

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

AU : IPC as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [*]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
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X,Y	AU,B, 66143/81 (535730) (ALZA CORPORATION) 23 July 1981 (23.07.81)	(1-8)
X,Y	AU,B, 68319/74 (482620) (ALZA CORPORATION) 30 October 1975 (30.10.75)	(1-8)
Y	AU,A, 22428/83 (CHESEBROUGH-POND'S INC.) 21 June 1984 (21.06.84)	(1-8)

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
16 October 1987 (16.10.87)	(28.10.87) 28 OCTOBER 1987
International Searching Authority	**Signature of Authorized Officer**
Australian Patent Office	C.M. WYATT

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON

INTERNATIONAL APPLICATION NO. PCT/AU 87/00255

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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END OF ANNEX